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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0067; FRL-10024-51]

Tolfenpyrad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tolfenpyrad in or on artichoke, globe. The Interregional Project Number 4 (IR-4) requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**). **ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2020-0067, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide

remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-

OPP-2020-0067 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2020-0067, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets*. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the *Federal Register* of May 8, 2020 (85 FR 27346) (FRL-10008-38), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8807) by the Interregional Project Number 4 (IR-4), Rutgers, The State University of New Jersey, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.675 be amended by establishing a tolerance for residues of the insecticide tolfenpyrad, (4-choro-3-ethyl-1-methyl-N-[[4-(4-methylphenoxy)phenyl]methyl]-1H-

pyrazole-5-carboxamide), in or on artichoke, globe at 5 parts per million (ppm). That document referenced a summary of the petition prepared by IR-4, the petitioner, which is available in the docket for this action, Docket ID EPA-HQ-OPP-2020-0067, at *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The toxicology database is considered complete. A variety of toxic effects were noted in the toxicology database for tolfenpyrad. However, the most consistent findings across species and studies were effects on bodyweight and bodyweight gain. Decreases in bodyweight and/or bodyweight gain were observed in adults of all species (rat, mice, rabbit, and dog) in the majority of the subchronic oral and dermal toxicity studies, and all chronic toxicity studies. Bodyweight decreases in rats were observed at much lower doses than in other species. Chronic exposure resulted in bodyweight and bodyweight gain decreases in mice and dogs at lower doses than the effects that were observed from acute and subchronic exposures. In addition, quantitative susceptibility was observed in the database; in the rat developmental study, decreased fetal weights and number of ossified metacarpals were observed in the absence of adverse maternal toxicity and in the one-generation reproduction study, decreased pup weights were observed at a lower dose than the dose at which parental bodyweight decreases reached biological significance. Tolfenpyrad is classified as "not likely to be carcinogenic to humans".

A complete discussion of the toxicological profile for tolfenpyrad as well as specific information on the studies received and the nature of the adverse effects caused by tolfenpyrad as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found in the document titled "Tolfenpyrad –

Human Health Risk Assessment of the New Use on Globe Artichoke" (hereinafter "Tolfenpyrad Human Health Risk Assessment") in docket ID number EPA-HQ-OPP-2020-0067 at *https://regulations.gov*.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (PODs) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides*.

A summary of the toxicological endpoints for tolfenpyrad used for human risk assessment can be found in the Tolfenpyrad Human Health Risk Assessment.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to tolfenpyrad, EPA considered exposure under the petitioned-for tolerances as well as all existing tolfenpyrad tolerances in 40 CFR 180.675. EPA assessed dietary exposures from tolfenpyrad in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for tolfenpyrad. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, the acute assessment assumed tolerance-level residues and 100% crop treated (PCT) for all commodities. Refinements include a factor to account for the reduction in residues when wrapper leaves are removed from head lettuce, radicchio, cabbage, Chinese Napa cabbage, and Brussels sprouts. Empirical processing factors were available for processed commodities of apple, orange, cottonseed, grape, plum, potato and tomato, and were translated to other crop processed commodities where appropriate. Where empirical processing factors were not available or were not translated, the Agency's 2018 default processing factors were used. Several factors were used to account for metabolite residues in/on bulb onion subgroup 3-07A commodities and livestock commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA's 2003-2008 NHANES/WWEIA. As to residue levels in food, EPA used average residues from field trials. The chronic assessment includes estimates of PCT for some crops and all the refinements described above for the acute assessment.

iii. *Cancer*. Based on the data cited in Unit III.A., EPA has concluded that tolfenpyrad does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information to establish the tolerance, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established,

modified, or left in effect, demonstrating that the residue levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, and the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The acute assessment assumes 100 PCT. The Agency incorporated estimates of average PCT in the chronic assessment for the following crops: grapefruit (15%), grapes (2.5%), lettuce (10%), onion (2.5%), oranges (5%), peppers (less than 2.5%), potatoes (2.5%), tangerines (2.5%), and tomatoes (2.5%).

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and California Department of Pesticide Regulation (CalDPR) Pesticide Use Reporting (PUR) for the chemical/crop combination for the most recent 10 years. EPA uses an average PCT for chronic dietary risk analysis and a maximum PCT for acute dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than 1% or less than 2.5%. In those cases, the

Agency would use less than 1% or less than 2.5% as the average PCT value, respectively. The maximum PCT figure is the highest observed maximum value reported within the most recent 10 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%, except where the maximum PCT is less than 2.5%, in which case, the Agency uses less than 2.5% as the maximum PCT.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which tolfenpyrad may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for tolfenpyrad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of tolfenpyrad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide*.

Residues of tolfenpyrad in surface and ground water were modeled with the Pesticide in Water Calculator (PWC Version 1.52). Groundwater estimated drinking water concentrations were modeled with the Pesticide Root Zone Model Groundwater (PRZM GW) model within the

Pesticide in Water Calculator (Version 1.52). For tolfenpyrad, the assessment uses the total residues approach, which is commonly used to assess chemicals that have residues of concern with similar toxicity to parent compound. The recommended estimated drinking water concentrations (EDWCs) for tolfenpyrad acute exposures are estimated to be 32.6 parts per billion (ppb) for surface water and 168 ppb for ground water. For chronic exposures for non-cancer assessments, EDWCs are estimated to be 14.1 ppb for surface water and 125 ppb for ground water. For the acute dietary exposure assessment, EPA used an EDWC of 168 ppm. For the chronic dietary exposure assessment, EPA used a value of 125 ppb.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Tolfenpyrad is not registered for any specific use patterns that would result in residential exposure. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to tolfenpyrad and any other substances, and tolfenpyrad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that tolfenpyrad has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at

https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There is no evidence of increased quantitative or qualitative susceptibility in the guideline rabbit developmental studies, the rat two-generation reproduction study, or the developmental immunotoxicity (DIT) study. Quantitative susceptibility was observed in the developmental rat study and the range-finding one-generation reproduction study. In the developmental rat study, decreased fetal weights and number of ossified metacarpals were observed in the absence of adverse maternal toxicity (only a 9% decrease in bodyweight). In the one-generation reproduction study, decreased pup weights were observed at a dose lower than the dose at which parental bodyweight decreases reached biological significance. All of the reviewed studies (developmental toxicity studies in the rat and rabbit and the one- and two-generation reproductive toxicity studies in the rat) include decreased bodyweight in the maternal LOAEL statement, as well as mortality in both of the developmental rabbit studies and the two-generation rat reproduction study. Reproductive toxicity was seen in rats as increased total litter loss in the two-generation study and decreased pup viability in the one- and two-generation study. Decreased pup weight was observed in all six studies, and additional offspring effects include: an increase in skeletal variation in both developmental toxicity studies; blackish abdominal cavity, dark green intestinal contents, and

decreased survival of offspring in the developmental immunotoxicity study; decreased pup viability in both reproduction studies, with the addition of a delay in developmental landmarks in the two-generation reproductive toxicity study. Since most of these effects occurred in the presence of comparable or more severe maternal toxicity, or were partially attributable to the maternal animal behavior, they were not considered evidence of qualitative susceptibility.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for tolfenpyrad is complete and includes acceptable developmental and reproductive toxicity studies.

ii. Based on the available toxicity database, there is no indication that tolfenpyrad is a neurotoxic chemical, and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. While there was evidence of quantitative susceptibility in two studies, the Agency's degree of concern for the susceptibility is low because the offspring effects consistently occurred at or near doses which caused maternal toxicity (bodyweight decrease), and because endpoints and doses selected for risk assessment are protective of the observed susceptibility.

iv. There are no residual uncertainties identified in the exposure databases. The dietary exposure assessment is partially refined but does not underestimate potential dietary exposure to tolfenpyrad. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to tolfenpyrad in drinking water. These assessments will not underestimate the exposure and risks posed by tolfenpyrad.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by

comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to tolfenpyrad will occupy 69% of the aPAD for children 1 to 2 years of age, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to tolfenpyrad from food and water will utilize 59% of the cPAD for all infants less than 1-year old, the population group receiving the greatest exposure. There are no residential uses for tolfenpyrad.

3. *Short-term and Intermediate-term risks*. Short-term and intermediate-term aggregate exposures take into account short-term and intermediate-term residential exposures plus chronic exposures to food and water (considered to be a background exposure level).

Short-term and intermediate-term adverse effects were identified; however, tolfenpyrad is not registered for any use patterns that would result in short-term or intermediate-term residential exposures. Short-term and intermediate-term risks are assessed based on short-term and intermediate-term residential exposures plus chronic dietary exposure. Because there are no short-term or intermediate-term residential exposures and chronic dietary exposures have already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term and intermediate-term risk), no further assessments of short-term and intermediate-term risks are necessary, and EPA relies on the chronic dietary risk assessment for evaluating short-term and intermediate-term risks for tolfenpyrad.

4. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, tolfenpyrad is not expected to pose a cancer risk to humans.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to tolfenpyrad residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An acceptable high-performance liquid chromatography method with tandem mass spectrometry detection (LC/MS/MS) is available for enforcement of tolfenpyrad residue tolerances in/on plant commodities (Morse Laboratories Analytical Method #Meth-183, Revision #2). For livestock, a method described in PTRL West Study No. 1841W is available. Residues are determined by LC/MS/MS analysis.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

The Codex has not established an MRL for tolfenpyrad in globe artichoke.

V. Conclusion

Therefore, a tolerance is established for residues of tolfenpyrad, (4-choro-3-ethyl-1-methyl-N-[[4-(4-methylphenoxy)phenyl]methyl]-1H-pyrazole-5-carboxamide), in or on artichoke, globe at 5 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these

types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 10, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.675, amend paragraph (a)(1) by designating the table and adding in alphabetical order in newly designated Table 1 to paragraph (a)(1) the entry "Artichoke, globe" to read as follows:

§ 180.675 Tolfenpyrad; tolerances for residues.

(a) * * *

(1) * * *

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
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Artichoke, globe	5
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[FR Doc. 2021-12609 Filed: 6/15/2021 8:45 am; Publication Date: 6/16/2021]